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NOTE

From: Presidency
To: Permanent Representatives Committee

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Subject: Proposal for a Regulation of the European Parliament and of the Council laying down harmonised rules on artificial intelligence (Artificial Intelligence Act) and amending certain Union legislative acts
- Preparation for the trilogue

DOCUMENT PARTIALLY ACCESSIBLE TO THE PUBLIC (10.11.2023)

INTRODUCTION

1. The Commission adopted the proposal for a Regulation laying down harmonised rules on artificial intelligence (Artificial Intelligence Act) on 21 April 2021.
2. The Council unanimously adopted its General Approach on the proposal on 6 December 2022.
3. The European Parliament (hereinafter: the EP) confirmed its position in a plenary vote on 14 June 2023.

4. Also on 14 June 2023, immediately after the vote in the EP, the co-legislators and the Commission held the first political trilogue on the AI Act, during which all three institutions outlined their priorities for the negotiations and the technical level was given a broad mandate to work on the entire proposal.
5. On 18 July 2023 the second political trilogue was held, during which some of the less controversial parts of the proposal were agreed and compromise was found on most elements of the chapter concerning measures in support of innovation.
6. On 2 and 3 October 2023 the third political trilogue took place in Strasbourg, during which further less controversial parts of the proposal were endorsed. In addition to this, the intention of the Presidency was to come to an agreement with the EP on three more controversial topics, namely the mechanism for the classification of AI systems as high-risk, the list of high-risk AI use cases, as well as subject matter and scope. However, talks on these topics proved inconclusive and no agreements were reached.
7. Since then four technical meetings with the EP have taken place, in order to prepare the next batch of provisions for agreement or for close alignment at the political level during the fourth political trilogue, which will take place on 24 October 2023 in Brussels.
8. Between 4 and 12 October 2023, the Presidency consulted the delegations, both during the meetings of the Working Party on Telecommunications and Information Society (hereinafter: WP TELECOM), and informally, on the compromise proposals and potential landing zones for agreement that are going to be discussed during the fourth political trilogue on 24 October 2023, and it has addressed all concerns expressed by the delegations, with regard to both the substance and the process for further negotiations.

II. POLITICAL ISSUES FOR POTENTIAL AGREEMENT DURING THE FOURTH TRILOGUE

9. The co-legislators intend to discuss the following three topics with a view to reaching a provisional agreement at political level during the fourth trilogue:

- **Classification of AI systems as high-risk** (Recitals 32 and 32a, Articles 6 and 7, Article 51, Article 65a (*new*), subparagraph 2 of Annex III (*new*) and Section D of Annex VIII (*new*))
- **List of high-risk AI use cases** (Annex III) [*with the exception of use cases related to biometrics and law enforcement authorities, which will be discussed together with Article 5 on prohibitions at a later stage*]
- **Testing high-risk AI systems in real world conditions outside AI regulatory sandboxes** (Articles 54a and 54b)

10. **DELETED**

11. **DELETED**

III. **DELETED**

12. **DELETED**



V. CONCLUSION

13. In light of the above, and with a view to obtaining a revised mandate for trilogue negotiations on the AI Act on 24 October 2023, the Permanent Representatives Committee is invited to:

- **indicate their flexibility with regard to the question presented in Part II of this note,**
 - **provide the Presidency with early feedback on the landing zones concerning the topics referred to in Part III of this note.**
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Articles 54a and 54b - Testing of high-risk AI systems in real world conditions outside AI regulatory sandboxes

	Commission Proposal	EP Mandate	Council Mandate	Presidency2
Article 54(2a)				
R	541b		<u>Article 54a</u> <u>Testing of high-risk AI systems in real world conditions outside AI regulatory sandboxes</u>	DELETED FROM THIS POINT UNTIL THE END OF THE COLUMN (page 17)
Article 54(2b), first subparagraph				
R	541c		<u>1. Testing of AI systems in real world conditions outside AI regulatory sandboxes may be conducted by providers or prospective providers of high-risk AI systems listed in Annex III, in accordance with the provisions of this Article and the real-world testing plan referred to in this Article.</u>	
Article 54(2b), second subparagraph				
R	541d		<u>The detailed elements of the real-world testing plan shall be specified in implementing acts adopted by the Commission in accordance with the examination procedure referred to in Article 74(2).</u>	
Article 54(2c)				

	Commission Proposal	EP Mandate	Council Mandate	Presidency2
R	541e		<u><i>This provision shall be without prejudice to Union or Member State legislation for the testing in real world conditions of high-risk AI systems related to products covered by legislation listed in Annex II.</i></u>	
Article 54(2d)				
R	541f		<u><i>2. Providers or prospective providers may conduct testing of high-risk AI systems referred to in Annex III in real world conditions at any time before the placing on the market or putting into service of the AI system on their own or in partnership with one or more prospective users.</i></u>	
Article 54(2e)				
R	541g		<u><i>3. The testing of high-risk AI systems in real world conditions under this Article shall be without prejudice to ethical review that may be required by national or Union law.</i></u>	
Article 54(2f)				
R	541h		<u><i>4. Providers or prospective providers may conduct the</i></u>	

	Commission Proposal	EP Mandate	Council Mandate	Presidency2
			<u>testing in real world conditions only where all of the following conditions are met:</u>	
Article 54(2f), point (a)				
R	541i		<u>(a) the provider or prospective provider has drawn up a real-world testing plan and submitted it to the market surveillance authority in the Member State(s) where the testing in real world conditions is to be conducted;</u>	R
Article 54(2f), point (b)				
R	541j		<u>(b) the market surveillance authority in the Member State(s) where the testing in real world conditions is to be conducted have not objected to the testing within 30 days after its submission;</u>	R

Article 54(2f), point (c)				
541k			<p><u>(c) the provider or prospective provider with the exception of high-risk AI systems referred to in Annex III, points 1, 6 and 7 in the areas of law enforcement, migration, asylum and border control management, and high risk AI systems referred to in Annex III point 2, has registered the testing in real world conditions in the EU database referred to in Article 60(5a) with a Union-wide unique single identification number and the information specified in Annex VIIIa;</u></p>	
Article 54(2f), point (d)				
5411			<p><u>(d) the provider or prospective provider conducting the testing in real world conditions is established in the Union or it has appointed a legal representative for the purpose of the testing in real world conditions who is established in the Union;</u></p>	

Article 54(2f), point (e)				
R	541m			<u>(e) data collected and processed for the purpose of the testing in real world conditions shall not be transferred to countries outside the Union, unless the transfer and the processing provides equivalent safeguards to those provided under Union law;</u>
Article 54(2f), point (f)				
R	541n			<u>(f) the testing in real world conditions does not last longer than necessary to achieve its objectives and in any case not longer than 12 months;</u>
Article 54(2f), point (g)				
R	541o			<u>(g) persons belonging to vulnerable groups due to their age, physical or mental disability are appropriately protected;</u>

Article 54(2f), point (h)

541p

(h) where a provider or prospective provider organises the testing in real world conditions in cooperation with one or more prospective users, the latter have been informed of all aspects of the testing that are relevant to their decision to participate, and given the relevant instructions on how to use the AI system referred to in Article 13; the provider or prospective provider and the user(s) shall conclude an agreement specifying their roles and responsibilities with a view to ensuring compliance with the provisions for testing in real world conditions under this Regulation and other applicable Union and Member States legislation;

Article 54(2f), point (i)

541q

(i) the subjects of the testing in real world conditions have given informed consent in accordance with Article 54b, or in the case of law enforcement, where the seeking of informed consent would prevent the AI

			<u>system from being tested, the testing itself and the outcome of the testing in the real world conditions shall not have a negative effect on the subject;</u>	
Article 54(2f), point (j)				
R	541r		<u>(i) the testing in real world conditions is effectively overseen by the provider or prospective provider and user(s) with persons who are suitably qualified in the relevant field and have the necessary capacity, training and authority to perform their tasks;</u>	R
Article 54(2f), point (k)				
R	541s		<u>(k) the predictions, recommendations or decisions of the AI system can be effectively reversed or disregarded.</u>	R

Article 54(2g)

541t

5. Any subject of the testing in real world conditions, or his or her legally designated representative, as appropriate, may, without any resulting detriment and without having to provide any justification, withdraw from the testing at any time by revoking his or her informed consent. The withdrawal of the informed consent shall not affect the activities already carried out and the use of data obtained based on the informed consent before its withdrawal.

Article 54(2h)				
R 541u			<p><u>6. Any serious incident identified in the course of the testing in real world conditions shall be reported to the national market surveillance authority in accordance with Article 62 of this Regulation. The provider or prospective provider shall adopt immediate mitigation measures or, failing that, suspend the testing in real world conditions until such mitigation takes place or otherwise terminate it. The provider or prospective provider shall establish a procedure for the prompt recall of the AI system upon such termination of the testing in real world conditions.</u></p>	
Article 54(2i)				
R 541v			<p><u>7. Providers or prospective providers shall notify the national market surveillance authority in the Member State(s) where the testing in real world conditions is to be conducted of the suspension or termination of the testing in real world</u></p>	

			<u>conditions and the final outcomes.</u>	
Article 54(2j)				
R	541w		<u>8. The provider and prospective provider shall be liable under applicable Union and Member States liability legislation for any damage caused in the course of their participation in the testing in real world conditions.</u>	R
Article 54b				
R	541x		<u>Article 54b Informed consent to participate in testing in real world conditions outside AI regulatory sandboxes</u>	R
Article 54b(1), first subparagraph				
R	541y		<u>1. For the purpose of testing in real world conditions under Article 54a, informed consent shall be freely given by the subject of testing prior to his or her participation in such testing and after having been duly informed with concise, clear, relevant, and understandable information regarding:</u>	R

541z

(i) the nature and objectives of the testing in real world conditions and the possible inconvenience that may be linked to his or her participation;
(ii) the conditions under which the testing in real world conditions is to be conducted, including the expected duration of the subject's participation;
(iii) the subject's rights and guarantees regarding participation, in particular his or her right to refuse to participate in and the right to withdraw from testing in real world conditions at any time without any resulting detriment and without having to provide any justification;
(iv) the modalities for requesting the reversal or the disregard of the predictions, recommendations or decisions of the AI system;
(v) the Union-wide unique single identification number of the testing in real world conditions in accordance with Article 54a(4c) and

			<u><i>the contact details of the provider or its legal representative from whom further information can be obtained.</i></u>	
Article 54b(2)				
R	541a a		<u><i>2. The informed consent shall be dated and documented and a copy shall be given to the subject or his or her legal representative.</i></u>	R

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